

—If applicable, information on the respondent's organization, including the type of organization (e.g., business, trade group, university, non-profit organization) and general areas of interest.

Parties presenting written comments are requested, where possible, to provide their comments in machine readable format. Such submissions may be provided by electronic mail messages sent over the Internet, or on a 3.5" floppy disk formatted for use in either a Macintosh or MS-DOS based computer. Machine-readable submissions should be provided as unformatted text (e.g., ASCII or plain text).

Written comments will be available for public inspection on or about March 1, 1995, in Room 902 of Crystal Park Two, 2121 Crystal Drive, Arlington, Virginia. In addition, comments provided in machine readable format will be available on or around March 1, 1995, through anonymous file transfer protocol (ftp) via the Internet (address: comments.uspto.gov) and through the World Wide Web (address: www.uspto.gov).

FOR FURTHER INFORMATION CONTACT: Jeff Kushan by telephone at (703) 305-9300, by fax at (703) 305-8885, by electronic mail at kushan@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231.

SUPPLEMENTARY INFORMATION:

I. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following guidelines establish the policies and procedures to be followed by Examiners when examining applications for compliance with the utility requirement of 35 U.S.C. 101. The guidelines also address issues that may arise during examination of applications claiming protection for inventions in the field of biotechnology and human therapy. The guidelines are accompanied by an overview of applicable legal precedent governing the utility requirement.

B. Guidelines for Examination of Applications for Compliance With 35 U.S.C. 101

Examiners must adhere to the following procedures when examining applications for compliance with 35 U.S.C. 101.

1. Determine what the applicant has claimed as his or her invention. This is done to:

(a) Ensure that the applicant has claimed statutory subject matter (e.g., a process, a machine, a composition or a manufacture); and

(b) Ascertain what the invention is for, purposes of determining whether it is "useful."

2. Review the specification and claims to determine if the applicant has disclosed or asserted any credible utility for the claimed invention.

(a) If the applicant has asserted that the claimed invention is useful for any particular purpose and that assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on section 101. Credibility is to be assessed from the perspective of one of ordinary skill in the art in view of any evidence of record (e.g., data, statements, opinions, references, etc.) that is relevant to the applicant's assertions.

(b) If the applicant has not asserted that the claimed invention is useful for a particular purpose but such a use would be readily apparent to a person of ordinary skill in the art, the Examiner should not impose a rejection under section 101.

3. If the applicant has not asserted any credible utility for the claimed invention or a utility would not be readily apparent to one of ordinary skill in the art, reject the claims under section 101. To be considered appropriate by the Office, a rejection under section 101 must include the following elements:

(a) A prima facie showing that the claimed invention has no utility. A prima facie showing of no utility must establish that it is more likely than not that a person of ordinary skill in the art would not consider credible any utility for the claimed invention that has been asserted by the applicant. Where no utility has been asserted in the disclosure, the prima facie showing must support a finding that a person of ordinary skill would not be able to ascertain any use for the claimed invention. A prima facie showing must contain:

(i) A well-reasoned statement by the Examiner that clearly sets forth the reasoning used in reaching his or her conclusions;

(ii) Support for factual findings relied upon by the Examiner in reaching his or her conclusions; and

(iii) Support for conclusions of the Examiner that evidence provided by the applicant to support an asserted utility would not be considered persuasive to a person of ordinary skill in the art.

(b) Evidence that supports any factual assertions relied upon by the Examiner in establishing the prima facie showing.

Whenever possible, the Examiner must provide documentary evidence that supports the factual basis of a prima facie showing of no utility (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents). If documentary evidence is not available, the Examiner should note this fact and specifically explain the scientific basis for his or her conclusions.

4. A rejection under section 101 should not be maintained if an asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art in view of all evidence of record.

Once a prima facie showing of no utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a printed publication, that rebuts the prima facie showing. Once a response has been received by the Examiner, he or she should review the original disclosure, any evidence relied upon in establishing the prima facie showing, any claim amendments and any new reasoning or evidence provided by the applicant in support of an asserted utility. It is essential that the Examiner recognize, fully consider and respond to each substantive element of any response to a rejection under section 101.

Examiners are reminded that they must treat as true credible statements made by an applicant or a declarant in the specification or in a declaration provided under 37 CFR 1.132, unless they can show that one of ordinary skill in the art would have a rational basis to doubt the truth of such statements. Thus, not accepting the opinion of a qualified expert that is based on an appropriate factual record would clearly be improper.

II. Additional Information

The PTO has prepared an analysis of the law governing 35 U.S.C. 101 to support the guidelines outlined above. Interested members of the public are invited to comment on the legal analysis as well as the guidelines. Copies of the legal analysis can be obtained from Jeff Kushan, who can be reached using the information indicated above.

Dated: December 23, 1994.

Bruce A. Lehman,

*Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks.*

[FR Doc. 94-32314 Filed 12-30-94; 8:45 am]

BILLING CODE 3510-16-M

DEPARTMENT OF ENERGY**Office of Civilian Radioactive Waste Management****Safe Transportation and Emergency Response Training; Technical Assistance and Funding**

AGENCY: Office of Civilian Radioactive Waste Management, Department of Energy.

ACTION: Notice of inquiry.

SUMMARY: The Department of Energy (the Department) intends to implement a program of technical assistance and funding to train State, local and tribal public safety officials of appropriate local jurisdictions with regard to the transport of spent nuclear fuel or high-level radioactive waste. The training would cover safe transport procedures and emergency responses. This notice briefly describes implementation options being considered, and members of the public are invited to comment.

The Department expects to hold public meetings in order to facilitate active public involvement in development of policies and procedures to administer the program.

DATES: Written comments should be mailed to the Department and must be received on or before April 3, 1995.

ADDRESSES: Written comments (3 copies) should be directed to: U.S. Department of Energy, c/o Lois Smith, TRW Environmental Safety Systems, 2650 Park Tower Drive, Suite 800, Vienna, Virginia 22180, ATTN: Section 180(c) Comments.

Persons submitting comments should include their names and addresses. Receipt of comments in response to this Notice will be acknowledged if a stamped, self-addressed postal card or envelope is enclosed.

FOR FURTHER INFORMATION CONTACT: For further information on the transportation of spent fuel and high-level radioactive waste under the Nuclear Waste Policy Act, please contact: Mr. Allen Benson, Operational Activities Team Leader, Office of Civilian Radioactive Waste Management (RW-45), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, D.C. 20585, Telephone: 1-202-586-2280. For general information on this Notice, please contact: Ms. Ellen Ott, Office of General Counsel, (GC-52), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, D.C. 20585, Telephone: 1-202-586-6975.

Information packets are available for interested persons who want background information about Office of

Civilian Radioactive Waste Management (OCRWM) transportation prior to providing comments. To receive an information packet, please call: 1-800-225-NWPA (or call 488-5513 in Washington, D.C.) or write to the OCRWM Information Center, Post Office Box 44375, Washington, D.C. 20026.

Copies of comments received will be available for examination and may be photocopied at the Department's public reading room at 1000 Independence Avenue SW, room 1E-190, Washington, D.C.

SUPPLEMENTARY INFORMATION:**Purpose and Need for Agency Action**

Under the Nuclear Waste Policy Act of 1982, as amended, (the Act) (42 U.S.C. 10101 *et seq.*), the Department is responsible for managing the disposal of spent nuclear fuel from civilian nuclear power plants and high-level radioactive waste, and for possible monitored retrievable storage of spent nuclear fuel prior to disposal. The Department is also responsible for transportation of spent nuclear fuel to the Department's disposal or storage site. In order to carry out these responsibilities, the Department needs to develop a policy and procedures to implement Section 180(c) of the Act which authorizes technical assistance and funds to States for training public safety officials of appropriate units of local government and Indian tribes in safe routine transport and emergency response through whose jurisdiction the Secretary of Energy plans to transport spent nuclear fuel. To ensure that the full range of issues and alternatives related to the policy and procedures is addressed, the Department invites comments regarding the scope and implementation mechanisms of Section 180(c).

Section 180(c) History

The Department's work to date on Section 180(c) policies and implementation procedures has been discussed primarily in three forums: Transportation Coordination Group meetings, Transportation External Coordination Working Group meetings and several cooperative agreements with national and regional organizations representing State, local and tribal constituencies. These groups have met and will continue to meet periodically to identify and discuss issues related to the transport of radioactive materials. This Notice of Inquiry begins a notice and comment process in the **Federal Register** that will broaden participation in the discussion of Section 180(c) policy and implementation procedures.

The Department has released two documents that discuss Section 180(c) policy and implementation in light of the current regulatory environment and stakeholder concerns. These two documents are the *Strategy for OCRWM to Provide Training Assistance to State, Tribal, and Local Governments* (November 1992, DOE/RW-0374P), and the *Preliminary Draft Options for Providing Technical Assistance and Funding Under Section 180(c) of the Nuclear Waste Policy Act, as Amended* (November 1992). These documents are available by requesting the information packet from the OCRWM Information Center.

The *Strategy* paper identifies certain planning principles and steps needed to implement Section 180(c). It also addresses stakeholder comments on the draft version of the document. The *Preliminary Draft Options* paper identifies various options available to the Department for implementing the funding and technical assistance requirements of the Act. The five option groups identified and discussed below are as follows: (1) Use established Federal agency programs other than the Department's, (2) establish agreements with State, local, tribal, and other organizations, (3) establish a Department-wide grant program, (4) establish an OCRWM grant program, or (5) select a mixed group of options comprising elements from the previous four groups.

The Department will further investigate the programs discussed in the *Preliminary Draft Options* paper to determine appropriate Section 180(c) policy and implementation procedures. The options, in greater detail, include:

(1) Use Established Federal Agency Programs Other Than the Department's

- The Federal Emergency Management Agency's Comprehensive Cooperative Agreement program (Civil Preparedness Guide: CCA General Program Guidelines, CPG 1-3/October 1992). The Federal Emergency Management Agency is responsible for coordinating emergency planning, preparedness, mitigation, and assistance functions of the Federal Government and as a part of that mission, the Comprehensive Cooperative Agreement mechanism channels financial and technical assistance through a single recipient for State and local governments.

- Department of Transportation's training and planning grants through the Hazardous Materials Transportation Act, as amended. This program, administered by the Department of Transportation's Research and Special

Programs Administration, provides for reimbursable grants and requires applicants to provide a 20 percent funding match to States and Tribes.

- Department of Transportation's Federal Highway Administration: Highway shipments are the responsibility of the Federal Highway Administration, which encourages nationally uniform inspection and enforcement activity among the States through the Motor Carrier Safety Assistance program (**Federal Register**, Vol. 57, No. 174, Tuesday, September 8, 1992, pp. 40946-64).

- Department of Transportation's Federal Railway Administration: Federal Government oversight of railroad inspections has been shared by the Interstate Commerce Commission and the Federal Railroad Administration (49 U.S.C. Subtitle V, Part A).

(2) Establish Agreements With State, Local, Tribal, and Other Organizations

The Department of Energy has cooperative agreements with the Commercial Vehicle Safety Alliance, Conference of Radiation Control Program Directors, Council of State Governments/Midwest, League of Women Voters Education Fund, National Association of Regulatory Utility Commissioners, National Conference of State Legislatures, National Congress of American Indians, Southern States Energy Board, and Western Interstate Energy Board. These agreements facilitate communication with stakeholders to provide information about the OCRWM program and to receive feedback and comments from the stakeholders about the program. Similar agreements could be established for Section 180(c) implementation.

(3) Establish a Department-wide Grant Program

Internal Department-wide coordination of emergency response activities is through the Transportation Emergency Preparedness Program (DOE Order 5500.1B). The Transportation External Coordination Working Group, discussed earlier, provides a mechanism for external parties to participate in the Department's coordination and development of emergency response activities. The following is an explanation of other Department transportation emergency preparedness activities that might serve as models of or vehicles for some or all of Section 180(c) implementation.

- Department of Energy's Waste Isolation Pilot Plant: The 1992 Waste Isolation Pilot Plant Land Withdrawal

Act (Pub. L. 102-579) has made financial and technical assistance to States and Tribes a legal requirement. Funds have been distributed to States through a cooperative agreement with the Western Governors' Association and with individual Tribes.

- Department of Energy's Environmental Restoration and Waste Management: The Office of Environmental Management is responsible for the development of all Department transportation policy with the exception of the transport of civilian spent nuclear fuel and high-level waste to a Nuclear Waste Policy Act facility and the transportation of weapons related materials or components. The office has funded transportation emergency response training for various Department shipments.

(4) Establish an OCRWM Grant Program

- Under this option, OCRWM would develop and implement its own program, specifically tailored to Section 180(c) requirements. The payment mechanisms could include a formula combining two or more grants, direct payments, or cooperative agreements.

(5) Use Elements From the Previous Four Groups

- Options from the preceding groups can be interchanged in a variety of ways. Since each option has elements that meet only portions of the Section 180(c) program requirements, it might be necessary to implement a variety of options.

Any Department decisions must weigh the applicability of each program option to Section 180(c) mandates to encompass safe routine transportation as well as emergency response capabilities over rail and highway modes for both State and Tribal recipients. In order to understand the benefits, costs and drawbacks of each program option, the Department will conduct an in-depth investigation of each program option.

Request for Submission

The Department solicits comments from the public on all aspects of Section 180(c) implementation, including but not limited to: Which option is the least administratively burdensome? Which option offers the greatest flexibility for recipients? What eligibility criteria do similar funding and training programs use? What formulas exist for division of funds among eligible parties? What restrictions should apply to the use of funds? How may funds be used in similar programs? What should be included under the term "technical

assistance"? Based on past experience, what types and scope of training activities would be appropriate for implementation under Section 180(c)?

Issued in Washington, D.C., December 28, 1994.

Lake Barrett,

Acting Director, Office of Civilian Radioactive Waste Management.

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Office of Energy Efficiency and Renewable Energy

[Case No. F-077]

Energy Conservation Program for Consumer Products: Decision and Order Granting a Waiver from the Furnace Test Procedure to York International

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Decision and Order.

SUMMARY: Notice is given of the Decision and Order (Case No. F-077) granting a Waiver to York International (York) from the existing Department of Energy (DOE) test procedure for furnaces. The Department is granting York's Petition for Waiver regarding blower time delay in calculation of Annual Fuel Utilization Efficiency (AFUE) for its P2LN and PBNL lines of condensing furnaces.

FOR FURTHER INFORMATION CONTACT:

Cyrus H. Nasser, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Mail Station EE-431, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9138.

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC-72, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9507.

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 430.27(g), notice is hereby given of the issuance of the Decision and Order as set out below. In the Decision and Order, York has been granted a Waiver for its P2LN and PBNL lines of condensing furnaces, permitting the company to use an alternate test method in determining AFUE.